Serial No.: 10/623,212 Filing Date: July 18, 2003

Group Art Unit: 3738 Examiner: Paul B. Prebilic

Atty. Docket No.: 22956-233 (MIT-230DIV)

### REMARKS

The pending Office Action addresses claims 61-69, 71-89, and 95. Applicant appreciates the Examiner's allowance of claims 72-74, and the Examiner's indication that claims 84-89 represent allowable subject matter. Remaining claims 61-69, 71, 75-83, and 95 stand rejected.

#### Amendments to the Claims

Per the Examiner's suggestion, Applicant amends independent claims 84 to insert "said insertion element." Applicant also amends independent claims 75 and 95 to specify that inserting the insertion element into the stabilizing element causes the stabilizing element to "deformably" expand. These amendments do not add any new matter, as the claims already recited a stabilizing element that deformably expands. Accordingly, entry after final is respectfully requested.

# Claim Objections

The Examiner objects to claim 84 as being confusing. As indicated above, Applicant amends claim 84 to insert "said insertion element" thereby obviating the basis for this objection.

# Claim Rejections Pursuant to 35 U.S.C. §103

The Examiner rejects claims 61-69, 71, 75-83, and 95 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,870,957 of Goble et al. ("Goble") in view of U.S. Patent 5,725,529 of Nicholson et al. ("Nicholson").

Independent claims 61, 75, and 95 each recite a method for anchoring soft tissue within bone including drilling an opening into bone, inserting a stabilizing element into the bone opening, threading soft tissue through an aperture in an insertion element, and inserting the insertion element into the stabilizing element. Inserting the insertion element into the stabilizing element is effective to deformably expand the stabilizing element.

In Applicant's previous response, Applicant explained that Goble does not teach or even suggest an insertion element that causes a stabilizing element to deformably expand, and that it would not have been obvious to modify Goble in view of Nicholson to have such a configuration

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because such a modification is specifically contrary to the teachings of Goble, and would render the Goble's anchor unsatisfactory for its intended purpose, which is to allow the anchor to be adjusted after implanted to thereby alter the tension on a ligament. In response to Applicant's arguments, the Examiner asserts that:

...the Applicant is assuming that a deforming expansion would necessarily deform the threads such as to prevent lateral movement of the footing. The Examiner asserts the claims do not require that such a large pressure be applied to deformably expand the footing that subsequent movement is prevented.

(Office Action dated June 28, 2007, p. 4). The Examiner appears to be asserting that the threaded footing of Goble could be modified such that the footing could be allowed to deformably expand without deforming the threads, thereby rendering the modification obvious because the modification could be made without ignoring the teachings of Goble.

At the outset, the Examiner's own rejection is clear evidence that the Examiner is improperly relying on hindsight to construct an obviousness rejection. The Examiner appears to agree that deformation of the threads of Goble would render the device unsatisfactory for its intended purpose. Thus, to overcome this, the Examiner simply asserts that only a portion of Goble could be modified without altering the threads to arrive at the claimed anchor, while still maintaining the structure of Goble that would allow it to serve its intended purpose. This modification is simply not taught or even suggested in the prior art. Neither Goble nor Nicholson include any teaching that would allow only a portion of the threaded footing to deform without deforming the threads, and neither reference includes any such teaching. Nicholson discloses an anchor having an expandable member that is fully deformed in order to lock the anchor within the bone tunnel. Nicholson's anchor does not include threads, and Nicholson does not disclose any techniques for allowing only a portion of the anchor to deform. Goble's threaded footing simply lacks any features that would be conducive to expansion – much less a partial expansion that deforms a portion of the footing but leaves the threads intact. Accordingly, there is simply no teaching or suggestion in Nicholson or Goble that would allow Nicholson's footing to be modified to deform without deforming the threads, and the Examiner is clearly relying on hindsight to construct an obviousness rejection.

There are also numerous additional reasons why no person having ordinary skill in the art would make the modification suggested by the Examiner. First, the Examiner has overlooked the

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fact that such a modification is impossible. There is simply no way to deform the footing without at least altering the threads. The footing is a cylindrical sleeve that is externally threaded along its length and is open through the middle. Any deformation of the sidewall of the footing would necessarily cause the threads to at least move outward and further into the surrounding bone. This would, however, interfere with removal or adjustment of the anchor, thereby ignoring the specific teachings of Goble which require that the anchor be configured to allow the footing to be rotated to adjust the tension of the ligament. Even if the threads remained in position, in order for the sidewall to deform at least a portion of the sidewall would have to move outward and in between the threads. This configuration would also interfere with removal or adjustment of the anchor. Accordingly, it would be impossible to modify the footing to deform while allowing the footing to be adjusted after it is implanted.

Even if the footing of Goble could somehow be modified to allow it to deformably expand while maintaining the functionality of the threads, such a modification would require a substantial reconstruction and redesign of the Goble device. For example, the modification would require any number of the following alterations: changing the thickness of the walls of the footing altering the material properties of the footing, reconfiguring the size and shape of the footing and/or the stud to allow the stud to cause the deforming expansion, and/or adding expansion features, such as slots, to the footing. The modification is therefore not a simple change that can be made through routine experimentation, but rather would require significant experiments and testing to produce such an anchor. There is also no reasonable expectation of success that the modification suggested by the

The Examiner has also overlooked that fact that such a modification would serve no purpose. Modifying the footing such that only a portion of the footing is deformed without deforming the threads would have little or no effect on the footing's ability to grip the walls of the bone tunnel, which is the primary purpose of the deformable expansion. The deformation would simply serve no purpose other than to interfere with use of the anchor, as it would make it more difficult to adjust the anchor as needed.

Accordingly, there are numerous reasons why no person having ordinary skill in the art would modify Goble in view of Nicholson, and therefore independent claims 61, 75, and 95, as well

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as claims 62-69, 71, and 76-83 which depend directly or indirectly therefrom, distinguish over Goble and Nicholson and represent allowable subject matter.

#### Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: Aug. 28,2007

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